REMARKS

Upon entry of the forgoing amendments claim 52 is pending in the application. Claims 53 and 54 have been cancelled without prejudice or disclaimer to the subject matter claimed therein. Basis for the amendment can be found in the application at page 6, paragraph 13; page 7, paragraph 16; page 9, Table I (protein 6); page 10, Table I (protein 16); page 11, line 7; and page 17, paragraph 27 through page 20, paragraph 24. Accordingly, the amendment does not introduce any new subject matter within the meaning of 35 U.S.C. §132. Therefore, entry of the amendment is respectfully requested.

OBJECTION TO CLAIM 54

The Examiner objected to claim 54 on the basis the claim contained a typographical error. Applicants have cancelled claim 54, thereby removing the basis for the objection. Therefore, the Examiner is respectfully requested to reconsider and withdraw the objection.

REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The Examiner has rejected claims 52-54 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Examiner stated:

> Claim 52 recites a method for diagnosing disorders associated with prostate cancer comprising contacting eukaryotic cells with peptides; however, the claims do not point out what result from said contacting would indicate that a subject has a particular disorder. Thus, there is a missing step involving correlating a specific result to a specific diagnosis.

Applicants respectfully traverse this rejection and submit that claim 52 has been amended to read:

> A method for diagnosing prostatic carcinomas, wherein eukaryotic cells are brought into contact with an antibody which is directed against proteins synthesized and/or secreted by carcinomas, wherein the proteins are selected from the group consisting of sialic acid synthase and KNP1-beta, and wherein an up regulation in the expression of said proteins is detected.

As such, the method now clarifies that an upregulation in the expression of sialic acid synthase and/or KNP1-beta is detected, thereby delineating the result for the claimed "contacting" that would indicate whether a patient is suffering from prostatic carcinoma. As a result claim 52 is clear and definite within the meaning of 35 U.S.C. §112, second paragraph.

Furthermore, claims 53 and 54 have been cancelled without prejudice or disclaimer to the subject matter recited therein, and therefore they are no longer subject to this rejection.

Based upon the foregoing, Applicants submit that the basis of this rejection has been removed in light of the amendment and cancellation of the remainder of the rejected claims. Therefore, the Examiner is respectfully requested to reconsider and withdraw this rejection.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH - WRITTEN DESCRIPTION

The Examiner has rejected claims 52-54 as failing to comply with the written description requirement as containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner states that the rejected claims are inclusive of two genera, specifically, a genus of peptides which detect expression or function of sialic acid synthase and a genus of peptides which detect expression or function of KNP1-beta. The Examiner continues by stating that the written description only sets forth, and the art only teaches, antibodies that specifically bind with sialic acid synthase.

Applicants respectfully traverse this rejection and submit that amended claim 52 fully complies with the written description requirement of 35 USC § 112, first paragraph. Claims 53 and 54 have been cancelled without prejudice or disclaimer to the subject matter contained therein, thereby removing them as a basis for this rejection.

The test under 35 U.S.C. 112, first paragraph, for determining compliance with the written description requirement is whether the application clearly conveys that an applicant has invented the subject matter which is claimed. *In re Barker*, 194 USPQ 470, 473 (CCPA 1977); MPEP 2163. Also, the applicant must convey to the public what the applicant claims as the invention so that the public may ascertain if the patent applicant claims anything in common use or already known. MPEP § 2163. Lastly, the specification must convey that the applicant was in possession of the invention. MPEP § 2163. The Examiner is respectfully reminded that he has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 191USPQ 90, 98 (CCPA 1976).

Claim 52 has been amended to a method of diagnosing prostatic carcinoma wherein eukaryotic cells are brought into contact with an antibody which is directed against proteins synthesized by the carcinoma, i.e., sialic acid synthase and/or KNP1-beta as diagnostic markers, and an upregulation of the proteins is detected. Sialic acid synthase and KNP1-beta are disclosed in the instant application in Table 1, pages 9, protein 6 and page 10, protein 16 respectively, as proteins synthesized and/or secreted by tumors according to the instant subject matter. Also, these proteins are shown as detected by the methods of this subject matter in Fig. 3, as points "6" and "16", and further described on page 20, paragraph 34. Specifically, Fig. 3 (Gel 9) shows the proteins found in tissue samples do include sialic acid synthase and KNP1-beta., i.e., that the expression of sialic acid synthase and KNP1-beta is upregulated in malignant prostatic tissue.

Additionally, Applicants respectfully submit the images in Attachement A, specifically PhosphorImager PR 47, which, like Fig. 3, shows points "6" and "16" and thus that sialic acid synthase and KNP1-beta are proteins found in tissue samples.

As such, claim 52 is in compliance with 35 U.S.C. §112, first paragraph for written description, since the subject matter at issue, namely the expression of sialic acid synthase and KNP1-beta, are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH - ENABLEMENT

The Examiner has rejected claims 52-54 as failing states that the specification does not reasonably provide enablement for a method for diagnosing just any disorder associated with just any type of tumor by contacting eukaryotic cells with just any peptide which detects the expression or function of just any protein synthesized or secreted by tumors. Applicants respectfully submit that claims 53 and 54 have been cancelled without prejudice or disclaimer to the subject matter contained therein, and as such are no longer basis for this rejection.

The enablement provision of the Patent Act requires that the patentee provide a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112, first paragraph (2000). The purpose of this requirement is to ensure that "the public knowledge is enriched by the

patent specification to a degree at least commensurate with the scope of the claims." *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999); *see also* Donald S. Chisum, 3 *Chisum on Patents* § 7.01 (2002).

Accordingly, the specification must provide sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). "The key word is 'undue,' not experimentation.'" *Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Routine experimentation does not constitute undue experimentation. *See Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998). That is, the specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation. *See, e.g., Nat'l Recovery Techs.*, 166 F.3d at 1196 ("The scope of enablement . . . is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation."); *Wands*, 858 F.2d at 736-37 ("Enablement is not precluded by the necessity for some experimentation such as routine screening."). "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *See In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

Although the ultimate determination of whether one skilled in the art could make and use the claimed invention without undue experimentation is a legal one, it is based on underlying findings of fact. *CFMT*, 349 F.3d at 1337. Furthermore, "[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Wands*, 858 F.2d at 737.

Some of these considerations, commonly referred to as "the *Wands* factors," include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of

the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.; see also Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (stating that the *Wands* factors "are illustrative, not mandatory" and that what is relevant to an enablement determination depends upon the facts of the particular case).

In the present case, Applicants assert that the specification, figures, and examples, provide ample guidance to the skilled artisan in view of the state of the art at the time the application was filed, to make and use the claimed invention without undue experimentation.

Specifically, amended claim 52 is directed the application of an antibody that is directed against sialic acid synthase and/or KNP1-beta. Such antibodies are well known to those of skill in the art and are routinely utilized in diagnostic immunoassays, such as ELISA. Those of skill in the art are familiar with the manufacture of such antibodies. For example, appropriate antibodies may be manufactured by administering fragments of proteins, such as epitopes, to animals that as a result produce specific antibodies against the fragments and epitopes, respectively.

Furthermore, the attached declarations under 37 C.F.R. §1.132 by Applicants Cahill, Wozny, Schrattenholz, and Klocker are submitted in order to show the enablement of the instant claims. Therein the Examiner is provided with results for corresponding experiments (Attachment A, as well as Figures and Examples of the application as-filed), which use differential quantitative proteomic procedure.

The dual isotope differential labeling of prostate cancer and benign prostate tissue allows a reliable and quantitative detection of differential (cancer associated) proteins, which are subsequently identified from gels by mass spectrometry. The underlying experimental strategy and the statistical treatment of potential biomarkers like the ones names in the present application are also the subject of recent publication (See,

Declarations).

As such claim 52 does reasonably provide enablement for a method for diagnosing prostatic carcinoma by contacting eukaryotic cells with an antibody which is directed against proteins synthesized and/or secreted by carcinomas, wherein the proteins are selected from the group consisting of sialic acid synthase and KNP1-beta, and wherein an up regulation in the expression of said proteins is detected.

Based upon the foregoing, Applicants submit that claim 54 is properly enabled. Therefore, the Examiner is respectfully requested to reconsider and withdraw this rejection.

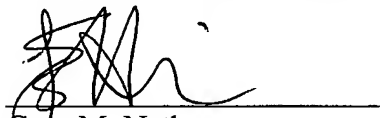
CONCLUSION

In view of the foregoing, Applicants respectfully request the Examiner to reconsider and withdraw the requirement for claim restriction and election of species and examine all claims pending in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,

THE NATH LAW GROUP



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January 14, 2008
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